

osity, comorbid burden using a method of risk adjustment based on pharmacy claims, and Part D uptake after adjusting for patients' demographic characteristics, characteristics of pre-Part D prescription use (average 2005 annual copayments, number of prescriptions, drug utilization in pill-days, number of treatment classes as reported in the store data), pre-Part D Medicaid eligibility, and zip code linked USA Census data. **RESULTS:** After multivariate adjustment, each 10% increase in 2005 insurance generosity was associated with a 16% lower likelihood of Part D utilization and each standard deviation increase in comorbid score was associated with an 8% greater likelihood of Part D utilization. Beneficiaries with the lowest yet positive insurance generosity with the greatest comorbid burden were up to 2.5 times more likely to utilize Part D than people who had generous insurance and were the healthiest before the introduction of the program (60.65% vs. 37.56%, $p < 0.001$). Results were robust to numerous sensitivity analyses. **CONCLUSION:** We find significantly higher rates of benefit adoption among subjects with low pre-Part D prescription coverage and high pre-Part D comorbid burden. Our findings highlight the fact that implementation and uptake of changes in health policy are seldom uniform. These results also may be useful in welfare analyses of Part D, and they demonstrate the importance of considering non-random selection into Part D when considering the impact of Part D on processes or outcomes of care.

MD8

THE IMPACT OF MEDICARE NEW DRUG BENEFIT (PART D) ON THE UTILIZATION OF PSYCHOTROPIC MEDICATIONS AND CONSEQUENT OUT OF POCKET EXPENDITURE FOR ELDERLY

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OBJECTIVE: To evaluate the effect of Medicare new drug benefit (Part D) on utilization of psychotropic medications and the consequent financial burden for elderly. **METHODS:** The effect of Medicare Part D was measured using 24 months pharmacy claims collected from one of the largest retail pharmacy chains in the United States. Among the approximately 70 million individuals who filled prescriptions at the pharmacy chain in 2006, 11% were 65 years or older. Segmented regression of interrupted time series analysis was employed to evaluate population level changes in the utilization of three most commonly used psychotropic therapeutic categories among elderly, namely antidepressants, antipsychotics and benzodiazepines. **RESULTS:** Since Part D came into effect, the proportion of out-of-pocket payment in total pharmacy reimbursement decreased 18% for antidepressants (net saving: \$4.5 per prescription) and 21% for antipsychotics (net saving: \$5.7 per prescription). In contrast, the out-of-pocket share the elderly paid for benzodiazepines increased 19% (net increase: \$2.8 per prescription). Part D implementation was associated with significant month-to-month increase in use of antidepressants [1679 prescriptions per month (95%CI:719, 2639)] and antipsychotics [567 prescriptions per month (95%CI:413, 720)]. By December 2006, the antidepressant and antipsychotic prescriptions filled by seniors grew 7% (from 273,166 to 293,590 prescriptions per month, $P < 0.001$) and 18% (from 41,079 to 48,276 prescriptions per month, $P < 0.001$) respectively as compared to the expected level estimated based on prior Part D trend. In contrast, Part D led to an immediate and sustained drop of 5% (from 238,961 to 226,622 prescriptions per month, $P < 0.001$) in benzodiazepine prescriptions filled by elderly. **CONCLUSION:** Our findings revealed that Medicare Part D improved the access to psychotropic medications covered

under plan through reducing out-of-pocket expenses. However, the financial burden related to psychotropic medications excluded from the Part D formulary, such as benzodiazepines, has significantly increased.

RESEARCH ON PATIENT REPORTED OUTCOMES METHODS

PM1

RASCH RATING SCALE ANALYSIS OF THE EQ-5D USING THE 2003 MEDICAL EXPENDITURE PANEL SURVEY (MEPS)

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The aim of this study was to assess the Rasch measurement properties of the EQ-5D in respondents with most prevalent chronic conditions. Medical Expenditures Panel Survey (MEPS) respondents' age ≥ 18 with complete EQ-5Ds from 2003 were extracted ($n = 19,439$). Eleven subgroups were identified using the primary ICD-9-CM code for the top 10 chronic conditions (hypertension, diabetes, depression, back disorder, arthropathy, cholesterol, asthma, sinusitis, anxiety and joint disorder) as well as healthy persons ($n = 8021$). Respondents with perfect scores demonstrating ceiling ($n = 3911$) and floor effects ($n = 3$) were removed to ensure uncertainty in the responses. Coding reflected that higher scores represent healthier respondents. The Rasch rating scale model was used to estimate one set of thresholds for all items. Unidimensionality was assessed using a z-score fit statistic, point-biserial correlations and Rasch residual factor analysis. Differential item functioning (DIF) was investigated in a pooled analysis of the 11 subgroups. Qualitative advances of the thresholds and positive point-biserial correlations were found on the EQ-5D items in all subgroups. Residual factor analysis revealed that a single factor explained between 74.9% and 94.4% of the variance. Further, respondents with different diseases demonstrated different orders of item difficulty. However, the item "anxiety/depression" consistently showed misfit ($z\text{-score} > 2.0$) in all subgroups. Overall, differential item functioning was found across the 11 subgroups, suggesting that respondents with different health conditions endorsed items with different frequency. For the most part, items in the EQ-5D contribute to a single underlying construct and may be used to evaluate different disease conditions. However, consistent item misfit of the "anxiety/depression" item in all subgroups suggests that a possible modification on this item may be needed.

PM2

WHAT PATIENTS SAY VS. WHAT PATIENTS MEAN: QUALITATIVE RESEARCH IN PRO DEVELOPMENT

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The value of qualitative research in the development of Patient-Reported Outcome (PRO) measures has been recognized for many years. Very little information is available, however, in the PRO field on the conduct and analysis of qualitative research compared to the plethora of literature that is readily available on psychometrics. More recently, the focus has been placed on the concepts being measured and their meaning, and not in terms of correlation coefficients or factorial structure, but in their authenticity for patients. This paper that is authored by an international, interdisciplinary group of psychologists, psychometricians, regulatory experts, a physician, and a sociologist presents a method for developing PROs that are based on a foundation of

rigorous qualitative research. This approach combines grounded theory methods and is underpinned by an overarching phenomenological framework. It is used to develop PRO items and scales that possess content validity and the ability to yield a measurement model for psychometric testing. This paper will present: 1) The rationale for the combination of these two schools of qualitative research; 2) the current tools that are used that include semi-structured interviews, a computerized software package, theoretical sampling, saturation and grounded theory data analysis methods; 3) examples of successful application of qualitative research to PRO development; and 4) future applications of qualitative research in upcoming/planned clinical trials.

PM3

THE VALIDITY AND RELIABILITY OF A PARENT-CHILD DYAD APPROACH TO UTILITY AND QUALITY-OF-LIFE ASSESSMENT IN CHILDREN

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OBJECTIVES: In children, utility and health-related quality of life (HRQOL) measurements may be influenced by age, cognitive ability and disease severity. Parents are often proxy respondents. The objectives were to assess the validity and reliability of a parent-child dyad utility and HRQOL assessment wherein children and parents are interviewed together to assess the child's HRQOL. **METHODS:** The Health Utility Index (HUI), PedsQL Core and Asthma Modules and the Pediatric Asthma Quality of Life Questionnaire (PAQLQ) were administered to 93 asthmatic children aged 8 to 15 years and their parents in a joint dyad interview. All questions were directed at the child to assess the child's utility and HRQOL. Questionnaires were scored normally. A pre-tested structured guide was available to interviewers. To assess construct validity of the dyad approach, Spearman correlations were calculated between HUI attributes and questionnaire domains associated with physical function and with emotional function. Test-retest reliability was assessed with an intra-class correlation coefficient (ICC) in 28 children who remained clinically stable between baseline and follow-up assessments at 5 months. **RESULTS:** Among the parent-child dyads, the HUI2 Mobility attribute was significantly correlated ($p < 0.05$) with the PedsQL Core Physical ($r = 0.41$) and the PAQLQ Activities ($r = 0.32$) domains. The HUI2 Emotion attribute was significantly correlated ($p < 0.05$) with the PedsQL Core Emotion ($r = 0.39$), the PedsQL Core Social ($r = 0.34$), the PedsQL Asthma Communication ($r = 0.21$) and the PAQLQ Emotion ($r = 0.25$) domains. For clinically stable children, significant ICCs between baseline and follow-up were observed for the HUI2 Total ($r = 0.53$), PedsQL Core Total ($r = 0.70$), PedsQL Asthma Symptoms ($r = 0.84$), PedsQL Asthma Treatment ($r = 0.51$), PAQLQ Activity ($r = 0.75$) and PAQLQ Emotion ($r = 0.76$) domains. **CONCLUSIONS:** The parent-child dyad demonstrated moderate construct validity and moderate to strong test-retest reliability in generic and disease-specific questionnaires. This approach may be a valid alternative to relying on parent proxies for assessing children's utility and HRQOL.

PM4

EVALUATION OF A THEORY OF GLOBAL HEALTH PREFERENCE FORMATION

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The multi-attribute health status (MAHS) approach to developing indirect utility measures assumes that health preferences are formed from the simultaneous consideration of multiple health dimensions. We propose an alternative view that theorizes the formation of health preferences is mediated by global impressions of quality of life (QL). This study compared the theory of global health preference formation (GHPF) with the MAHS approach for explaining time trade-off utilities. A total of 1432 cancer patients completed the EORTC QLQ-C30 and valued their own current health. A mediation analysis was performed using latent variable models relating health preferences to QLQ-C30 domains. Founded on the MAHS approach, Model I described health preferences using the physical, role, cognitive, emotional, and social functioning domains (PF, RF, CF, EF, and SF, respectively) and the fatigue (FA), pain (PA), and nausea/vomiting (NV) symptom domains. Model II related the QL domain to the same functioning and symptom domains. Consistent with the GHPF framework, Model III purported that QL mediated associations of health preferences with functioning and symptoms. Ignoring QL, health preferences were related to PF ($b = 0.041/p = 0.050$), SF ($b = 0.057/p = 0.028$), and EF ($b = -0.054/p = 0.001$). Model II: QL was positively related to RF ($b = 0.222/p = 0.001$), EF ($b = 0.116/p = 0.001$), SF ($b = 0.257/p < 0.001$), FA ($b = 0.245/p < 0.001$), and PA ($b = 0.123/p = 0.001$). Model III: QL was positively related to health preferences ($b = 0.117/p < 0.001$). Controlling for QL, the only functioning or symptom domain related to health preferences was EF ($b = -0.067/p < 0.001$). Significant indirect effects representing differences between direct effect estimates for Models I and III were observed for RF ($b = 0.026/p = 0.001$), EF ($b = 0.014/p = 0.002$), SF ($b = 0.030/p < 0.001$), FA ($b = 0.029/p = 0.003$), and PA ($b = 0.014/p = 0.002$). Model III provided a significantly better fit than Model I ($p < 0.001$). The MAHS approach yields misspecified models of health preferences since QL mediates associations of the latter with functioning and symptoms. Our framework has far-reaching implications for utility assessment and warrants further research.

PODIUM SESSION III

RESEARCH IN ADHERENCE AND COMPLIANCE I

ACI

THE ASSOCIATION BETWEEN IMPROVEMENTS IN DRUG ADHERENCE AND SHORT-TERM SERVICE UTILIZATION AND COSTS IN A MEDICAID POPULATION

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OBJECTIVE: More than one-third of patients with diabetes exhibit poor adherence with recommended drug regimens. While poor adherence is associated with excess morbidity and mortality, it is important to realize that better adherence may also affect short-term health care costs. This research quantifies the effects of improvements in medication adherence on short-term health services utilization and their associated costs. **METHODS:** Data from Florida: A Healthy State (FAHS), a Medicaid disease management program developed jointly by Pfizer Inc. and the state of Florida targeting chronically ill Primary Care Case Management